

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on April 7, 2003.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office no later than 5 p.m. on Monday, March 24, 2003.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 125.9, 148, 685 and 4005 of the Business and Professions Code and Section 56.36 of the Civil Code, and to implement, interpret or make specific Sections 125.9, 148 and 685 of said Code and Section 56.36 of the Civil Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 125.9 authorizes the board to establish by regulation, a system for issuing citations and fines up to \$2,500 for violations of the Pharmacy Law (Business and Professions Code 4000 et seq.) and any regulations adopted pursuant thereto.

Business and Professions Code Section 148 authorizes the board to establish by regulation, a system for issuing citations and fines for up to \$2,500 to persons who act in the capacity of a licensed person under the jurisdiction of the board without benefit of a license (i.e., unlicensed practice).

Business and Professions Code Section 685 permits the board to issue a citation and fine to any currently licensed health care practitioner that defaults on specified student loans.

Business and Professions Code Section 4005 authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

Business and Professions Code Section 4067 authorizes the board to issue a citation with a fine of up to \$25,000 per violation for dispensing a dangerous drug or dangerous device over the internet when the person knew or reasonably should have known the prescription was not based on a good faith medical examination.

Business and Professions Code Section 4127.4 authorizes the board to issue a citation with a fine of

up to \$2,500 per occurrence for violations relating to the compounding of sterile injectable drug products.

Civil Code Section 56.36 authorizes the board to issue citations and fines for up to \$250,000 to its licensees for violation of the Confidentiality of Medical Information Act (Civil Code 56 et seq.).

1. Amend Section 1775

This proposal would delete references to a committee of the board and instead requires the executive officer or his/her designee to issue citations, and would specify the violations that are subject to a citation.

2. Adopt Section 1775.1

This proposal would:

- a. Specify the maximum fine permitted for specified violations;
- b. Specify that failure to pay a fine within 30 days may result in disciplinary action against the licensee.
- c. Require that when a fine is not paid, the amount of that fine is added to the renewal fee for that license and that the license cannot be renewed without payment of the renewal fee and fine.

3. Repeal Section 1775.15

This section is being repealed because the proposed regulation would require the Executive Officer or his/her designee to issue all citations.

4. Amend Section 1775.2

This section is being amended to delete provisions incorporated in other sections relating to the issuance of citations and the dollar value limitation on fines and to delete reference to a committee of the board as the issuing entity.

5. Amend Section 1775.3

This section is being amended to increase clarity and to delete language incorporated in 1775.1.

6. Amend Section 1775.4

This section is amended to update obsolete references and to replace board inspectors and board members with the executive officer and his/her designee. The section is also amended to make clarify changes and to require that an office conference be held within 30 days of a request.

7. Repeal Sections 1777-1777.5 and 1778-1778.3)

These sections are being repealed because the provisions of these sections have been consolidated in prior sections.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses:

The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:

The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has determined that the proposed regulations would not affect small businesses. The proposed regulations affect internal board operations and would have no effect on small businesses.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814, or from the Board of Pharmacy website (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Paul Riches
Address:	400 R Street, Suite 4070 Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x 4016
Fax No.:	(916) 327-6308
E-Mail Address:	Paul_Riches@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
Address:	400 R Street, Suite 4070 Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x4005
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E-Mail Address:	Virginia_Herold@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.